SUPPORTING STATEMENT
State Enforcement Notifications
21 CFR 100.2(d)
0910-0275

A. JUSTIFICATION

1. Describe circumstances that make the information collection necessary

Section 310(b) (21 U.S.C. 337(b)) of the Federal Food, Drug, and Cosmetic Act (the act) authorizes States to enforce certain sections of the act in their own names (Attachment A). A State's ability to exercise this authority is predicated upon the State giving notice to the FDA that it intends to bring such proceeding 30 days before instituting action. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State (Attachment B).

This is a request for extension by OMB of its approval of the information collection requirements in the following citation:

21 CFR 100.2(d) - Reporting

Describes the information to be in a notification from a State advising FDA of the State's intent to initiate enforcement of certain requirements of the Federal Food, Drug, and Cosmetic Act.

2. How, by Whom, and for What Purpose the Information is Used

Section 310(b) of the act provides that States must submit notice to FDA before taking action to enforce certain provisions of the food misbranding provisions of the act. This information will be used by the agency in reaching a conclusion as to whether Federal action is being or will be taken against the same product that is under consideration for action by the State.

The regulation providing for State notification of enforcement actions, §100.2, has been in effect since February 5, 1993. The FDA has received just a small number of notifications of the intention of a State to initiate an enforcement action under the provisions of section 310(b) of the act since then. In each case, FDA has advised the State that it had no ongoing action and that the State could proceed with its enforcement action. Based upon its experience with these notifications of enforcement action, FDA believes that the current provisions of §100.2 are adequate and do not need revision.

3. Use of Improved Information Technology

The regulation for State notices of intended enforcement actions does not specifically prescribe the use of automated, electronic, mechanical or other technological techniques or other forms of information technology as necessary for use by the States. States are free to use whatever forms of information technology may best assist them in their development of a notice.

4. Identification of Duplication and Similar Information Already Available

The notification provisions of §100.2(d) eliminate the possibility that Federal action against a food for violation of the Federal law would be duplicated by a State. Because the enforcement provisions are limited to labeling provisions of the act that are enforced by FDA, there is no likelihood of duplication by Federal agencies.

5. Small Businesses

The provisions of this regulation are specific to State governments and are not applicable to small businesses.

6. Consequences if Data were Collection Less Frequently

There are no consequences to Federal program or policy activities if the information is not collected or is collected less frequently. Under section 310(b) of the act, a State's standing to bring an action under the act is predicated on the State submitting a letter of notification to FDA. Therefore, if the letter of notification is not submitted, the State cannot institute an action to enforce a provision of the act.

7. Special Circumstances

There are no special circumstances associated with this information collection.

8. Outside Consultation

In accordance with 5 CFR 1320.8(d), on Tuesday, June 8, 1999 (64 FR 30525), a 60-day notice for public comment (Attachment C) was published in the Federal Register. No comments were received from the public

9. Gifts

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality

State notifications to FDA under section 310(b) of the act will contain information compiled for law enforcement purposes and may contain trade secrets or confidential commercial or financial information. Accordingly, §100.2(i) provides that information contained in the required notification will be exempt from public disclosure to the same extent to which such information would be so exempt under 21 CFR 20.61, 20.64, and 20.88.

11. Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Respondent Hour Burden and Annualized Burden Hour Costs Estimates

Burden Hours.

FDA estimates the total annual burden for this collection will be insignificant. Enforcement notifications have infrequently been submitted in the recent past; none have been submitted in the last three years. Because §100.2(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate.

Estimated Annual Reporting Burden[1]					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.2(d)	1	1	1	10	10

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for Sec. 100.2(d) is insignificant because enforcement notifications are seldom submitted by States requesting the agency take enforcement action under the act against a particular food. Over the last 3 years, FDA has not received any enforcement notifications. Since the enactment of section 403A(b) of the act (21 U.S.C. 343-1(b)) as part of the Nutrition Labeling and Education Act of 1990, FDA has received only a few enforcement notifications.

Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403(A)(b) of the act.

Estimated Annualized Cost for the Burden Hours.

FDA estimates annualized hour burden cost to respondents for completion and submission will be insignificant. Estimated cost for completion and submission = $750.

13. Annual Cost Burden to Respondent

There are no capital costs or operating and maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA estimates that annualized cost to the Federal government for the review and evaluation of petitions submitted under §100.2(d) will be $1,250.

15. Changes or Adjustments in Burden

There is no change in burden.

16. Statistical Analysis, Publication Plans, and Schedule

The information obtained from this data collection will not be published.

17. Approval Not to Display Expiration Date

No approval requested.

18. Exception to the Certification Statement Identified in Item 19

No exceptions to the certification statement identified in item 19 of the instructions for completing OMB form 83-I have identified.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no plans to publish the information collected under the provisions of this regulation for statistical use. The collection of information required under the provisions of this regulation does not employ statistical methods.